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FIBROGEN, INC. 409 Illinois Street San Francisco, CA 94158				
EXAMINER				
DESAI, ANAND U				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/529,708

Applicant(s)

YANG ET AL.

Examiner

ANAND U. DESAI

Art Unit

1656

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 December 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-56 is/are pending in the application.
- 4a) Of the above claim(s) 22-26, 29-36 and 39-56 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9, 16-21, 27, 28, 37 and 38 is/are rejected.
- 7) ☒ Claim(s) 10-15 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 March 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsman's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of group I, claims 1-21, 27, 28, 37, and 38, drawn to a tissue sealant composition in the reply filed on December 10, 2008 is acknowledged. The traversal is on the ground(s) that the special technical feature does link the inventions of the present invention. Applicant's state the special technical feature is that the crosslinking agent of the tissue sealant composition does not react with the synthetic collagen or with synthetic gelatin, but, wherein, upon contact of the tissue sealant composition with an environment comprising about a physiological pH, the crosslinking agent reacts with the synthetic collagen or the synthetic gelatin. This is not found persuasive because the prior art has shown the lyophilization of collagen, wherein the collagen is used as a tissue sealant.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 22-26, 29-36, and 39-56 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on December 10, 2008.

3. Claims 1-21, 27, 28, 37, and 38 are currently under examination.

Priority

4. Acknowledgment is made of applicant's claim for priority under 35 U.S.C. 119(e). The priority date is September 30, 2000.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 1-5, 8, 9, 16, 17, 18, 20, 27, 28, 37 and 38 rejected under 35 U.S.C. 103(a) as being unpatentable over Maddalo et al. (U.S. Patent 6,454,787 B1) and Weinberg (U.S. Patent 4,837,379).

In short, the focus when making a determination of obviousness should be on what a person of ordinary skill in the pertinent art would have known at the time of the invention, and on what such a person would have reasonably expected to have been able to do in view of that knowledge. This is so regardless of whether the source of that knowledge and ability was documentary prior art, general knowledge in the art, or common sense. "A person of ordinary skill in the art is also a person of ordinary creativity, not an automaton." *KSR*, 550 U.S. at ___, 82 USPQ2d at 1397. "[I]n many cases a person of ordinary skill will be able to fit the teachings of multiple patents together like pieces of a puzzle." *Id.* Office personnel may also take into account "the

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inferences and creative steps that a person of ordinary skill in the art would employ.” Id. at ___, 82 USPQ2d at 1396. In addition to the factors above, Office personnel may rely on their own technical expertise to describe the knowledge and skills of a person of ordinary skill in the art. The Federal Circuit has stated that examiners and administrative patent judges on the Board are “persons of scientific competence in the fields in which they work” and that their findings are “informed by their scientific knowledge, as to the meaning of prior art references to persons of ordinary skill in the art.” *In re Berg*, 320 F.3d 1310, 1315, 65 USPQ2d 2003, 2007 (Fed. Cir. 2003).

Prior art is not limited just to the references being applied, but includes the understanding of one of ordinary skill in the art. The prior art reference (or references when combined) need not teach or suggest all the claim limitations, however, Office personnel must explain why the difference(s) between the prior art and the claimed invention would have been obvious to one of ordinary skill in the art. The “mere existence of differences between the prior art and an invention does not establish the invention’s nonobviousness.” *Dann v. Johnston*, 425 U.S. 219, 230, 189 USPQ 257, 261 (1976).

Maddalo et al. disclose a hemostatic device prepared by the process comprising: (a) suspending a plurality of collagen particles in water to form a collagen slurry, wherein the collagen particles have a bulk density sufficient to form a suspension in water and wherein the collagen slurry has a collagen concentration in the range of about 1% to about 2% (weight/volume); and (b) lyophilizing the collagen slurry to form a hemostatic device. The process can further comprises the step of crosslinking the hemostatic device to form a crosslinked-hemostatic device, thus the art has disclose the use of a lyophilized

collagen (dry) which can be further cross-linked in the presence of a crosslinking agent (see also col. 5, lines 28-35). The composition can further comprise a hemostasis-promoting amount of at least one hemostatic agent effective to accelerate clot formation at an interface between a wound surface and the hemostatic device. The composition can further comprise the step of introducing into the hemostatic device, a therapeutically-effective amount of at least one therapeutic agent (see claims 9-16).

Weinberg discloses the use of cross-linking to enhance strength and stability of a collagen composition that involves mechanical handling (see col. 3, lines 9 and 10, and col. 4, lines 3-6).

The prior art as evidenced by Maddalo et al. has disclosed the cross-linking of a lyophilized collagen composition that has been used for hemostasis.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make a tissue sealant composition comprising a crosslinking agent and a synthetic collagen in a dry state to treat bleeding and adhesion, because Maddalo et al. discloses the use of a dry collagen composition for hemostasis. Additional motivation to cross-link the dry composition is provided by the known desire to have a stronger and stable composition which requires mechanical handling as evidenced by the disclosure in Weinberg. Therefore, the invention would have been *prima facie* obvious to the person having ordinary skill in the art at the time the invention was made.

8. Claims 6, 7, 19 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Maddalo et al. (U.S. Patent 6,454,787 B1) and Weinberg (U.S. Patent 4,837,379) as

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applied to claims 1-5, 8, 9, 16, 17, 18, 20, 27, 28, 37 and 38 above, and further in view of Epstein et al. (U.S. Patent 6,045,570).

Maddalo et al. and Weinberg are discussed above.

Epstein et al. disclose the use of gelatin as a material for use as a biological sealant to treat hemostasis (see claims 1-15 and 33).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to make a tissue sealant composition comprising a crosslinking agent and a synthetic gelatin in a dry state to treat bleeding and adhesion, because Epstein et al. discloses the use of a dry milled gelatin composition for use as a sealant. Additional motivation to cross-link the dry composition is provided by the known desire to have a stronger and stable composition which requires mechanical handling as evidenced by the disclosure in Weinberg. Therefore, the invention would have been *prima facie* obvious to the person having ordinary skill in the art at the time the invention was made.

Claim Objections

9. Claims 10-15 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

10. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANAND U. DESAI whose telephone number is

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(571)272-0947. The examiner can normally be reached on Monday - Friday 9:00 a.m. - 5:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber can be reached on (517) 272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

March 16, 2009
/ANAND U DESAI/
Primary Examiner, Art Unit 1656